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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,225	12/03/2003	Burkhard Jaeger	1/1433	5189

28501 7590 08/13/2004

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EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,225

Applicant(s)

JAEGER ET AL.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14 is/are rejected.
- 7) ☒ Claim(s) 10-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of The Claims

Currently claims 1-15 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the resolution method described in the said claims using some chiral carrier material, does not reasonably provide enablement for:

- Carrying out the said process with any possible chiral carrier material.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prepare the invention commensurate in scope with these claims. See MPEP 2164.01

Some of the factors considered in the present rejection are:

The Nature of the Invention

The invention is drawn to *resolution methods of racemic mixtures*. Essential to the said separation technique is the chemical nature of the material inducing the separation between the enantiomers. It is very unlikely that all chiral carriers materials would have the same chemical nature required to separate the compounds subjected to resolution as described in the claims.

The State of the Prior Art and The level of Predictability in the Art

The resolution techniques up to the moment are very specific regarding the chemical structure of the enantiomers being separated and the chiral material use in its separation.

Since a person skilled in the art would not expect that the resolution can be carried out with any chiral-agent, a patent granting the said general process would obscure a whole research area without any benefit to the public.

The existence of working examples

The specification of the instant invention only provides 4 examples wherein particular chiral carrier materials are successfully use in achieving the enantiomeric resolution.

The said materials are similar in its chemical nature; it carbamate derivatives. There is no support that the said examples can be translated as to any chiral carrier material in order to perform the claimed separations.

Experimentation required to make the invention

A person skilled in the art would need to carry out undue experimentation when using other chiral carriers in order to achieved the resolution. The said work will need to be directed to identify the proper conditions, if any, wherein the technique of HPLC can be adapted to the chiral carriers in order to perform the separation, as well as to identify the conditions such asw temperature, mixture amounts, column types, flow rate, mobile phase etc. See for instance Kumar et al, *Journal of Chromatography*, Vol. 678 (1994) pp. 259-263, wherein the separation of some enantiomer derivatives was achieved using B-cyclodextrin stationary phase and notice the complexity of the interaction

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between chiral agents and compounds subjected to resolution. Base upon the above factors, the specification does not provide any teaching to a person skill in the art to use all possible chiral carriers material in the separation of the enantiomers described in the instant claims without undue experimentation. See *In re Wands*, 8 USPQ 2d 1400 and *In re Wright* 27 USPQ 2d 1510.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "chiral carrier material" is indefinite because it is unclear what materials can satisfy the limitations of the process claimed.

In claims 8 and 9, the phrase "modified polysaccharide" is indefinite. What polysaccharides are embraced in the said phrase? How the said modification was achieved? What is the resulting product of the said "modification?"

In claim 9, the phrase "polysaccharide which contains one or more optically active groups" is indefinite. What organic moieties are embraced in the said "groups"? What other organic moieties are excluded? Which polysaccharides are embraced in the said terms?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Tabuchi et al, Tetrahedron Letters, vol. 34(14) pp. 2327-2230.

Tabuchi discloses a method for the preparation of Alternaric acid. In the said preparation 5-hydroxy tertbutyl keto ester 15 is reacted with a base in order to prepare the valerolactone identified as compound 3, see Scheme 3, page 2238.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tabuchi et al, Tetrahedron Letters, vol. 34(14) pp. 2327-2230.

Tabuchi discloses a method for the preparation of Alternaric acid. In the said preparation 5-hydroxy tertbutyl keto ester 15 is reacted with a base in order to prepare the valerolactone identified as compound 3, see Scheme 3, page 2238.

Tabuchi does not disclose the preparation tipranavir by ciclyzation of 5-hydroxy-3-ketoester that would provide the said derivative.

Nonetheless, it would be obvious to use a different substance-known or novel- in a conventional method-*such as those described by the term "methods known per se"* in order to achieved the production of a compound already predicted by the prior art.

Claims Objected

Claims 10-13 are objected because of its dependency from rejected claims 1 and 8.

CONCLUSION

Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is 571-272-0691. The examiner can normally be reached on Monday to Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner 's supervisor, Ms. Rita Desai, which telephone number, is 571-272-0684. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or for regular communication and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Héctor M. Reyes PhD, JD

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August 8, 2004

R. Desai
8/9/04.